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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,335	09/22/2003	Francesco Borrelli	BORRELLI2A	8379

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EXAMINER	
O HARA, EILEEN B	

ART UNIT	PAPER NUMBER
1646	

MAIL DATE	DELIVERY MODE
09/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/666,335	BORRELLI ET AL.	
	Examiner	Art Unit	
	Eileen B. O'Hara	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 May 2007 and 05 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 5, 2007 has been entered.

Claim Status

2. Claims 20-24 are pending in the instant application. Claims 20-23 have been amended, and claim 24 been added as requested by Applicant in the Paper filed May 3, 2007.

All claims are currently under examination.

Withdrawn Objections and Rejections

3. Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 20-24 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a pharmaceutical composition comprising a TNF antagonist, does not reasonably provide enablement for a pharmaceutical composition comprising a TNF antagonist and either hCG, LH or FSH. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claims are directed to a pharmaceutical composition for treating infertility comprising an anti-TNF antibody or a fragment thereof, a pharmaceutically acceptable carrier, and a biologically active hormone selected from the group of human chorionic gonadotrophin (hCG), luteinising hormone (LH) and follicle stimulating hormone (FSH). The specification demonstrates that administering TNF antagonists ameliorates endometriosis, and a pharmaceutical composition comprising a TNF antagonist is enabled. However, the pharmaceutical composition comprises a TNF antagonist and either hCG, LH or FSH. The specification teaches at page 12:

The TNF antagonist can be administered prophylactically or therapeutically to an individual prior to, simultaneously or sequentially with other therapeutic regimens or agents (e.g. multiple drug regimens), in a therapeutically effective amount, in particular for the treatment of infertility. TNF antagonists that are administered simultaneously with other therapeutic agents can be administered in the same or different compositions. In particular, when infertility is the endometriosis associated disorder intended to be cured, biologically active human chorionic gonadotrophin (hCG), luteinizing hormone (LH) or follicle stimulating hormone (FSH), either in a natural highly purified or in a recombinant form, can be administered.

However, the art teaches that patients suffering from endometriosis should be treated with antagonists of those hormones, not with the hormones. Sharpe et al., Current Concepts in Endometriosis, 199), pages 449-458, teaches the effective use of gonadotropin releasing hormone (GnRH) antagonists in treating endometriosis (cited in IDS).

Ling, U.S. Patent No. 5,037,805, teaches that antagonists of FSH are useful for treating endometrisis:

(33) The availability of mammalian FSH-IP peptides permit their use as mammalian contraceptives for both males and females. These peptides should also be useful in the treatment of other conditions which are caused by an overabundance of FSH or estrogen, for example, endometriosis and certain types of breast cancer. Administration of substantially pure monoclonal antibodies to FSH-IP peptides have potential therapeutic applications to treat cases of infertility.

Funk et al., U.S. Patent No. 5,710,247, teaches that an antagonist to luteinising hormone releasing hormone can be used to regulate the secretion of FSH, chorionic gonadotropin and LH in mammals, and can be used to treat endometriosis. At column 1, lines 11-50, Funk et al. states:

The gonadotropins: follicle stimulating hormone (FSH), luteinizing hormone (LH), and chorionic gonadotropin (CG), are required for ovulation, spermatogenesis, and the biosynthesis of sex steroids. A single hypothalamic hormone, gonadotropin-releasing hormone GnRH (also known as luteinizing hormone-releasing hormone, LHRH) is responsible for regulating the secretion of both FSH and LH in mammals.

The literature has reported that LHRH analogs are useful for the treatment of a variety of conditions in which the suppression of sex steroids plays a key role including contraception, delay of puberty, treatment of benign prostatic hyperplasia, palliative treatment or remission of hormonal-dependent tumors of the breast and ovaries, palliative treatment or remission of

hormonal-dependent tumors of the prostate, the treatment of cryptoorchidism, hirsutim in women, gastric motility disorders, dysmenorrhea, and endometriosis.

Since the art teaches away from the pharmaceutical composition, it is not enabled for use in treating endometriosis.

Additionally, even if the pharmaceutical composition were enabled for treating endometriosis, it would not be enabling for treating infertility. While endometriosis might result in infertility, not all infertility is caused by endometriosis. There are other etiologies that can cause infertility. Madsen, U.S. Patent No. 5,389,657, teaches in column 1:

(3) Infertility effects an estimated 1 in 5 couples in the United States. The Merck Manual, p. 1768 (16th Ed. 1992). About 40 percent of infertilities are due to male deficiency, 40-50 percent to female anatomic or hormonal defects, and the remainder to indeterminate factors. 17 McGraw-Hill Encyclopedia of Science and Technology, p. 417 (6th Ed. 1987).

(4) Infertility refers to the inability to conceive during the course of normal sexual activity. However, a couple is generally not regarded as infertile until they have failed to conceive after one year of unprotected intercourse. Diagnosis and treatment of infertility requires a thorough assessment of both partners. The Merck Manual, p. 1768 (16th Ed. 1992).

(5) The major factors leading to female infertility include: ovulatory dysfunction; abnormal tubular function; and cervical factors. In addition to these three factors, other undetermined factors also cause infertility. An undefined factor may be a compromised ability of the egg/embryo to produce a functioning fertilization envelope or withstand toxic effects of oxidants.

Conclusion

5. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (571) 272-0878. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nichol can be reached at (571) 272-0835.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://portal.uspto.gov/external/portal/pair. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Eileen B. O'Hara, Ph.D.

Patent Examiner